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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,225	06/30/2003	David Hung	005284.00198	1750
38732 7590 02/07/2007 CYTYC CORPORATION 250 CAMPUS DRIVE MARLBOROUGH, MA 01752			EXAMINER SANG, HONG	
			ART UNIT 1643	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE 3 MONTHS		MAIL DATE 02/07/2007	DELIVERY MODE PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/608,225		HUNG ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Hong Sang		1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-7, 9 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 9 and 13-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

**RE: Hung et al.**

1. Applicant's response filed on 12/7/2006 is acknowledged. Claims 1-3, 5-7, 9, and 13-15 are pending. Claim 4, 8, 10-12 and 16-70 are cancelled. Claims 1 and 9 are amended.
2. Claims 1-3, 5-7, 9 and 13-15 are under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Due to species election, claims are examined to the extent that the estrogen activity modulator is an estrogen antagonist.
5. The effective filing date for the claims 1-3, 5-7, 9 and 13-15 is 5/17/1999 (see previous office action mailed on 9/6/06).

***Objections Withdrawn***

6. The objection to the first line of the specification for failing to reference to the earlier filed application is withdrawn in view of the ADS filed on 6/30/03, which references to both prior filed applications i.e. 09/313,463, and 60/117,281.

Applicants amended the first line of specification in the response to reference to the application no. 09/313,463, now US patent 6,638,727. To be consistent with the ADS, applicants are suggested to amend the first line of the specification to include the provisional application 60/117,281.

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7. The objection to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code is withdrawn in view of applicants' amendment to the specification.

8. The objection to claim 9 because it depends in part on a non-elected claim, i.e. claim 8 is withdrawn in view of applicants' amendment to the claim.

9. The objection to claim 4 as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view of applicants' cancellation of the claim.

10. The objection to claim 9 as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view of applicants' persuasive arguments.

***Rejections Withdrawn***

11. The rejection of claim 1 because the last part of the claim does not correlate completely with the preamble is withdrawn in view of applicants' amendment to the claim.

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12. The rejection of claim 5 under 35 U.S.C. 112, second paragraph because it is unclear whether the sample is obtained from the same patient or from any patient or subject is withdrawn in view of applicants' persuasive arguments.

***Response to Arguments***

13. The rejection of claims 1-3, 9 and 13-15 under 35 U.S.C. 102(b) as being anticipated by Fabian et al. (J. Cell Biochem., 1993, 17G: 153-160, IDS) is maintained.

The response states that Fabian et al. does not teach or suggest a method of obtaining ductal fluid from a patient and Fabian et al. teaches a method of obtaining ductal cells by use of fine needle aspiration. The response states that fine needle aspiration is an invasive technique by which a needle is inserted through a patient's breast and, in the present case, into the tissue behind the nipple in an attempt to sample terminal ducts (page 2; left column; third paragraph) and no ductal fluid was sampled by the method of Fabian et al.

Applicants' arguments have been carefully considered but are not found persuasive. First of all, the instant claims do not limit the method of obtaining a ductal fluid to a non-invasive method. Fabian et al. teach that the needle was placed almost perpendicular to the chest wall and tissue behind nipple was probed deeply in an attempt to sample the terminal ducts (see page 154, 1<sup>st</sup> paragraph under METHODS). Fabian et al. teach that the ductal epithelial cells are examined cytologically and cancer markers including the estrogen receptor are determined (see page 154, right column). Because the ductal epithelial cells were successfully collected by the needle aspiration,

it indicates that the needle was inserted into the terminal ducts, as such the sample collected by the needle aspiration would include ductal fluid (secretions) and ductal epithelial cells. Moreover, applicants have not provided any evidence to show that a needle aspiration would not collect ductal fluid when the needle is in the duct. Because of these reasons, the rejection is deemed proper and therefore is maintained.

14. The rejection of claims 1-3, 5, 6, 8 and 13-15 under 35 U.S.C. 102(b) as being anticipated by Sauter et al. (British J. Cancer, 1997, 76(4): 494-501, IDS) is maintained.

The response states that Sauter et al. do not teach the limitation cited in the wherein clause and wherein clause was indeed a limitation of the claim (see *In Griffin v. Bertina* (285 F.3d 1029, 62 USPQ2d 1431 (Fed. Cir. 2002))), and should be given patentable weight.

Applicant's arguments have been carefully considered but are not found persuasive. The instant claims are directed to a method for identifying asymptomatic patients who have a likelihood of benefiting from the administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer comprising determining the presence of precancerous or cancerous ductal epithelial cells. Sauter et al. teach a non-invasive method for early detection of breast cancer comprising collecting nipple aspirate fluid from a patient, cytologically analyzing the fluid (e.g. computerized image analysis of nipple aspirate fluid epithelial cells), and evaluating the promising cancer markers, wherein said patients were categorized by their risk for breast cancer as having no risk factors, a first degree relative with breast cancer, a

history of curative treatment for ductal carcinoma in situ (DCIS), or invasive breast cancer, precancerous mastopathy (atypical hyperplasia (AH) or lobular carcinoma in situ (LCIS) or recently diagnosed invasive cancer of the breast (see abstract and page 495, left column, 2<sup>nd</sup> paragraph). Sauter et al. teach that the nipple aspirate fluid cytology correlated with increased breast cancer risk ( $P=0.002$ ) (see abstract). Moreover, the whole purpose of the early detection of breast cancer is for early treatment of the breast cancer, which has been appreciated by Sauter et al. (see page 494, left column, 2<sup>nd</sup> paragraph, lines 1-2). The breast cancer would likely to benefit from administration of an estrogen activity modulator. Therefore, the teachings of Sauter et al. anticipate the instant claims.

The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case. In *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court held that when a “whereby” clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention.” *Id.* However, the court noted (quoting *Minton v. Nat’l Ass’n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed.Cir. 2003)) that a “whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.” *Id.* < (see MPEP 2111.04[R-3]).

MPEP 7.37.10 states “A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for

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completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951)".

15. The rejection of claims 1-3, 6-7 and 13-15 under 35 U.S.C. 102(b) as being anticipated by JAMA (JAMA, 1973, 224 (6): 823-827) is maintained.

Applicants presented same arguments as set forth above (see paragraph 14). The response states that since JAMA fails to teach the limitation recited in the wherein clause, it cannot anticipate the instant claims.

Applicants' arguments have been carefully considered but are not found persuasive for the same reasons set forth above (see paragraph 14). The JAMA reference discloses using the claimed method, Dr. Sartorius has found eight carcinomas, which are all found in the breast of a patient who had appeared asymptomatic and had been missed by mammography (see page 826, right column, 5<sup>th</sup> paragraph). The purpose of the early detection of breast cancer is for early treatment of the breast cancer. The breast cancer would likely to benefit from administration of an estrogen activity modulator. Therefore, the teachings of JAMA reference anticipate the instant claims.

The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case. In *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court held that when a "whereby" clause states a condition that is material to patentability, it cannot be ignored in order to



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change the substance of the invention.” Id. However, the court noted (quoting *Minton v. Nat’l Ass’n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed.Cir. 2003)) that a “whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.” Id. < (see MPEP 2111.04[R-3]).

MPEP 7.37.10 states “A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951)”.

16. The rejection of claims 1-3, 5-7 and 15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 13, 15 and 19-21 of U.S. Patent No. 6,610,484B1 is maintained.

The response states that application 10608,225 and US 6,610,484 were at the time the instant invention was made owned by Cytoc Corporation.

Applicants’ arguments have been carefully considered but are not found persuasive. The fact that the instant application and US 6,610,484B1 were at the time the instant invention was made owned by the same company can not overcome the rejection. Filing a terminal disclaimer would overcome the rejection.

17. The rejection of claims 1, 6, 7, and 15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 11, 13 and 22 of U.S. Patent No. 6,642,009B2 is maintained.

The response states that application 10608,225 and US 6,642,009B2 were at the time the instant invention was made owned by Cytoc Corporation.

Applicants' arguments have been carefully considered but are not found persuasive. The fact that the instant application and US 6,642,009B2 were owned by the same company at the time the instant invention was made cannot overcome the rejection. Filing a terminal disclaimer would overcome the rejection.

### ***Conclusion***

18. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang, Ph.D.  
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Jan. 19, 2007

  
CHRISTOPHER H. YAEN  
PRIMARY EXAMINER